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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/225,502	01/06/99	MOORE	

HM22/1027

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EXAMINER	
DECLOUX, A	
ART UNIT	**PAPER NUMBER**
1644	6

DATE MAILED: 10/27/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/225,502	Moore, P. et al
Examiner	**Group Art Unit**
Amy DeCloux	1644

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) *11-14 and 16-20* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-10 and 15* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. The examiner of your application In the PTO has changed. Upon review of the instant application, it is noted that there is no direction given for entering the Paper Copy of the sequences In the specification. Please clarify.

2. Formal drawings have been submitted which comply with 37 CFR 1.84.

3. A restriction was required under 35 USC 121 between (one of the following groups):

I. Claims 1-10 and 15, drawn to nucleic acids encoding ligand, vectors, transformants and expression thereof, classified in Class 536, subclass 23.1, Class 435, subclasses 69.1, 252.3, 320.1,

II. Claims 11,12,14 and 16, drawn to an isolated polypeptide, classified in Class 530, subclass 350,

III. Claim 13, drawn to an isolated antibody, classified in Class 530, subclass 387.9,

IV. Claim 17, drawn to a method for treating a medical condition with a polypeptide, classified in Class 514, subclass 12,

V. Claim 18, drawn to a method of diagnosing a pathological condition by determining the presence of a mutation on the polynucleotide of claim 1, classified in Class 435, subclass 6,

VI. Claim 19, drawn to a method of diagnosing a pathological condition by determining the expression of the polypeptide of claim 11, classified in Class 435, subclass 7.1, and

VII. Claim 20, drawn to a method of identifying a binding partner of claim 11, classified in Class 435, subclass 4.

4. Inventions I and V, Inventions II and IV/VII, and Inventions III and VI, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the nucleotide product encompassed by Invention I can be used in a process of making a DNA vaccine, as well as in a process of diagnosing a pathological condition by determining the presence of a mutation on the polynucleotide, as encompassed by claim V.

In the instant case, the antibody product as encompassed by Invention III, can be used in a materially different process such as an affinity purification procedure, as well as in a process of diagnosing a pathological condition by determining the expression of distinct polypeptides, as encompassed by Invention VI.

In the instant case, the peptide products encompassed by Invention II, can be used as an antigen for the production of antibodies, as well as in a method for treating a medical condition as encompassed by Invention IV, or in a method of identifying its binding partner, as encompassed by Invention VII.

5. Inventions IV, V/VI, and VII are different methods encompassing methods to treat a medical condition, diagnose a pathological condition, and identify a binding partner, respectively, and accordingly, require different ingredients, process steps and endpoints. Inventions V and VI encompass different methods with the same endpoint of diagnosing a pathological condition, and accordingly, require different ingredients and process steps, with Invention V requiring the use of a polynucleotide, and Invention VI requiring the use of a polypeptide. Therefore, Inventions IV/V/VI/VII are patentably distinct.

6. Inventions I, II and III are different products, encompassing nucleic acids, a polypeptide and an antibody. Nucleic acids, polypeptides and antibodies are distinct because their structures and modes of action are different, which require non-coextensive searches. Therefore, they are patentably distinct.

7. During a telephone conversation with Anders Brookes, on 7/22/99, a provisional election was made with traverse to prosecute Invention I, claims 1-10 and 15. Affirmation of this election must be made by applicant in responding to this Office action. Accordingly, claims 11-14 and 16-20 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a nonelected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, In such full, clear, concise, and exact terms as to enable any person skilled In the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-5, 7-10 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-5, 7-10 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for nucleic acid molecule encoding SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, and SEQ ID NO:8, does not reasonably provide enablement for a nucleic acid molecule comprising a nucleotide sequence encoding an amino acid sequence at least 95% identical with residues 27-336 of SEQ ID NO:2, and residues 1-441 of SEQ ID NO:4, and residues 25-574 of SEQ ID NO:6 and residues 1-388 of SEQ ID NO:8. First, SEQ ID NO:2 encodes a polypeptide that encompasses only 316 residues, not 336 residues as encompassed by claim 1. Second, SEQ ID NO:6 encodes a polypeptide that encompasses only 541 residues, not 574 residues as encompassed by claim 1.

Additionally, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. Factors to be considered in determining whether undue experimentation is required are summarized In *In re Wands* (858iF2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. Besides the polynucleotides encoding polypeptides with the sequences SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, and SEQ ID NO:8, respectively, the specification fails to provide guidance as to how to make or use the claimed polynucleotide encoding a polynucleotide with at least an 95% identity to the claimed sequences. Page 13 of the instant specification defines a polypeptide having an amino acid sequence of 95% identity to a reference amino acid sequence of any of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, and SEQ ID NO:8, where the polypeptide would be identical to the reference sequence except the polypeptide sequence may include up to five amino acid substitutions per each 100 amino acids (see page 13, lines 1-5, In particular).

Additionally, up to 5% of the reference sequence may be deleted, substituted or inserted (see page 13, lines 5-7), In particular). Although methods for determining the percent identity are disclosed In the specification, such as the computer program FASTDB, only preferred methods used by the applicant have been disclosed, and accordingly the specification is not limited to the computer program FASTDB. The use of "percent" in conjunction with any of the various terms that refer to sequence similarity is a problem since sequence identity between two sequences has no common meaning within the art. The term "percent" can be defined by the algorithm and parameter values set when using the algorithm used to compare the sequences. The scoring of gaps when comparing one sequence to another introduces uncertainty as to the percent of similarity between two sequences. Therefore, the scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acid encoding the amino acid sequences broadly encompassed by the claims due to the significant number of untaught sequences. Therefore, there is no evidence of record to show that one skilled In the art would be able to practice the invention as claimed without an undue amount of experimentation.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance In the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

11. Claims 1-5, 7-10 and 15 are rejected under *35 U.S.C. § 112*, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 1 and its dependent claims 2-5, and 7-10 and 15, are indefinite because of "residues 27-336 of SEQ ID NO:2" and "residues 25-574 of SEQ ID NO:6". SEQ ID NO:2 encodes a polypeptide that encompasses only 316 residues and SEQ ID NO:6 encodes a polypeptide that encompasses only 541 residues. See paper copy of said sequences in the instant disclosure. Please clarify.

B) Claim 5 is indefinite because the instant claim refers to nucleotides 3-1166 of the nucleotide sequence of the nucleic acid molecule of claim 1. However, it is not clear which of the four nucleic acid molecule(s) that encode discrete residues of amino acid sequences of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, and SEQ ID NO:8, encompassed by claim 1 are being referred to since residues 27-336 of SEQ ID NO:2 and residues 25-474 of SEQ ID NO:6, when back translated from their respective amino acid sequence to a nucleic acid sequence, comprise nucleic acid molecules that consist of less than 1166 nucleotides. See paper copy of said sequences in the instant disclosure. Please clarify.

C) Claim 9 is indefinite since it is not clear what is meant by "A host cell comprising the vector or claim 7." (Underline added) Please clarify.

D) The applicant is reminded that any amendment must point to a basis in the specification so as not to add any new matter.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made In this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described In a printed publication In this or a foreign country or In public use or on sale In this country, more than one year prior to the date of application for patent In the United States.

13. Claims 1, 2, 3, 5, and 6-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Simek et al (Genomics, 18:407-409, 1993), as evidenced by MPSEARCH US-09-225-502-2 and MPSEARCH US-09-225-502-4.

Simek et al. teach that the nucleic acid sequence of GenBank Accession No. L07063 encodes a novel FK506-binding protein, based on the translation of said nucleic acid sequence to an amino acid sequence (see entire article, especially page 407, column 1 second paragraph, first two sentences). A protein data base search of PIR using MPSEARCH (TM) shows residues 39-84 of said protein taught by Simek et al., (GenBank Accession No. L07063) comprise at least 30 contiguous amino acid residues of SEQ ID NO: 2, which correspond to nucleic acids 117-254 of SEQ ID NO: 1, and that residues 465-496 of said protein taught by Simek et al. comprise at least 30 contiguous amino acid residues of SEQ ID NO: 4, which corresponds to nucleic acid residues 973-1068 of SEQ ID NO: 3. (See Result No.1 on pages 1 and 2 of a protein data base search of PIR using MPSEARCH entitled US-09-225-502-2 and also Result No.1 on pages 1 and 2 of a protein data base search of PIR using MPSEARCH entitled US-09-225-502-4).

Given the use of the term "comprising" in claim 1, and given that claim 1 does not clearly state that the "95% identical " portion of the sequence encompasses the entire length of the sequence between the recited residues, art, such as that taught by Simek et al, which reads on at least 95% identity on only a portion of the sequences encompassed by part (a) and (b) of claim 1, and claims 2, 3, and 5, applies in a 102(b) rejection. Due to the ambiguity of claim 5 (see Section 10B), for examination purposes, claim 5 refers back to SEQ ID NO:2 and SEQ ID NO: 4 encompassed by claim 1.

Simek et al. also teach that the nucleic acid sequence of GenBank Accession No. L07063 was isolated from a cDNA expression library (see entire article, especially the Abstract and page 407, column 1 second paragraph, first two sentences). Since it was well known in the art at the time the invention was made that cDNA expression libraries encompass host cells and vectors with a heterologous regulatory promoter containing the nucleic acid molecule of interest, claims 7-10 read on the art taught by Simek et al.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced sequences.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 6-10 and 15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Simek et al. (Genomics, 18:407-409, 1993), in view of the well known art in molecular biology using cDNA expression libraries at the time the invention was made.

Claims 6-10 and 15 encompass host cells and vectors containing nucleic acid molecules of claim 1, heterologous regulatory elements which control the expression of said nucleic acid molecules, and a method of expressing and recovering the encoded polypeptide using host cells comprising said regulatory elements and said nucleic acid molecules.

Simek et al. teaches as above, however, they do not explicitly teach a specific vector, host cell, heterologous regulatory element, nor do they explicitly state their method of expressing and recovering the polypeptides.

However, one of ordinary skill in the art at the time the invention was made would have been motivated use the host cells and vectors with heterologous regulatory elements, that were well known components in the well known art of using cDNA expression libraries to express and recover a protein of interest, as taught by Simek et al who used a mouse JB6 epidermal cell cDNA expression library expression library to isolate the nucleic acid sequence of GenBank Accession No. L07063, encompassed by the nucleic acid molecules of claim 1 (see entire article, especially the Abstract and page 407, column 1 second paragraph, first two sentences).

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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October 25, 1999

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